

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

PHILIP MORRIS USA INC. et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION et al.,

Defendants.

Civil Action No. 1:15-cv-1590

**PLAINTIFFS' MOTION FOR RECUSAL AND MEMORANDUM OF LAW IN  
SUPPORT OF RECUSAL**

Pursuant to 28 U.S.C. § 455(a) and (b)(2), Plaintiffs Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, R.J. Reynolds Tobacco Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., and ITG Brands LLC respectfully request that the Court recuse itself from this case. The Court previously was a partner in the Washington, D.C. office of Zuckerman Spaeder LLP and has disclosed that, during that period, lawyers at the firm “provided legal counsel” to the Campaign for Tobacco-Free Kids (“CTFK”) “relating to the comments that it submitted” to the Food and Drug Administration (“FDA”) advocating the regulatory action that Plaintiffs are challenging in this case. Response to Informational Request, ECF No. 24, at 1 (Oct. 30, 2015) (“Response”). Zuckerman Spaeder’s representation of CTFK in connection with the agency action at issue in this case, during the time that the Court was a partner in the firm, requires recusal under Section 455(b)(2) because “a lawyer with whom [the Court] previously practiced law served during such association as a lawyer concerning the matter [in controversy].” 28 U.S.C. § 455(b)(2). Recusal is also required under Section 455(a) because Zuckerman Spaeder’s work on this matter—as well as on other

matters on behalf of anti-tobacco groups—and the Court’s close personal ties with that firm create grounds on which the Court’s “impartiality might reasonably be questioned.” 28 U.S.C. § 455(a).

For each of those reasons, the Court should step aside from this case.<sup>1</sup>

### **BACKGROUND**

This case presents a challenge to a “guidance” document issued by FDA entitled *Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2) (Sept. 8, 2015) (“Second SE Directive”)* (AR001-37). The Second SE Directive purports to confer on FDA the authority to pre-approve tobacco product label changes and changes in the quantities in which tobacco products are packaged. Plaintiffs allege that the Directive is unlawful and unconstitutional because, among other reasons, it contravenes the structure and plain language of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), violates the substantive and procedural requirements of the Administrative Procedure Act, and infringes Plaintiffs’ First Amendment rights.

FDA first announced that it was considering new restrictions on tobacco product label changes in a “draft guidance” document issued in September 2011. *See Draft Guidance for Industry and FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Sept. 2011) (“Draft Directive”)* (AR083-95). In the Draft Directive, FDA declared that a label change creates a “new tobacco product” under Section 910(a)(1)(B) of the Tobacco Control Act because a product label “is considered a ‘part’ of that

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<sup>1</sup> Pursuant to Local Rule 7(m), Plaintiffs have conferred with Defendants’ counsel about the relief requested in this motion, and Defendants are reserving their position until they have reviewed the as-filed motion.

product.” *Id.* at 3 (AR087). FDA solicited comments from the public on the Draft Directive. 76 Fed. Reg. 55,927-28 (Sept. 9, 2011) (AR478-79).

On November 8, 2011, CTFK jointly submitted comments on the Draft Directive with several other groups. AR179-203. CTFK urged the increased regulation of tobacco products by FDA and endorsed FDA’s position that “the label and packaging of a tobacco product is a ‘part’ of that product.” AR186. In April 2013, in response to comments submitted by tobacco manufacturers—including several of the Plaintiffs here—CTFK submitted additional comments to FDA on the Draft Directive. AR214-95; *see also* AR214 (“[T]he purpose of these comments is to respond to arguments made by the tobacco product manufacturers . . .”). Among other points, CTFK specifically took issue with comments in which Philip Morris USA Inc. (“PM USA”) and U.S. Smokeless Tobacco Company LLC (“USSTC”) explained that a label is not a “part” of a tobacco product and that a change to the label would not create a “new tobacco product” within the meaning of the Tobacco Control Act. *See* AR266-67. In response, CTFK criticized the statutory arguments advanced by PM USA and USSTC for supposedly “miss[ing] the point,” argued that “it is altogether reasonable for FDA to conclude that the indicium of a name change coincides with and identifies a ‘new tobacco product,’” and asserted that PM USA and USSTC were “wrong when [they] allege[d] that the Tobacco Control Act,” as construed by FDA in the Draft Directive, “creates a prior restraint against the renaming of a substantially equivalent product.” AR266, 267. PM USA and USSTC submitted comments replying to CTFK’s comments in June 2013.

FDA subsequently issued a final directive on March 4, 2015, entitled Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Mar. 4, 2015) (“First SE Directive”) (AR061-82). The directive

imposed premarket review requirements on tobacco product label changes that, in FDA's view, render the product "distinct" as well as on changes to the quantity in which tobacco products are packaged.

On April 14, 2015, Plaintiffs filed suit challenging the First SE Directive. *See Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, No. 15-544 (D.D.C.). The case was originally assigned to Hon. Ellen S. Huvelle, whose spouse is an attorney at Covington & Burling, LLP, one of the firms representing Plaintiffs; the case was thereafter randomly reassigned to this Court. Shortly thereafter, FDA announced that it would evaluate potential changes to the First SE Directive and issued an "Interim Enforcement Policy" in which it agreed not to enforce the Directive's requirements while that review was ongoing. First SE Directive at 1 n.1 (AR040). In light of that review process and Interim Enforcement Policy, Plaintiffs dismissed their suit without prejudice.

FDA issued the Second SE Directive on September 8, 2015. The Second SE Directive did not materially modify the requirements that the First SE Directive imposed regarding FDA premarket review of changes to tobacco product labels and product quantity, but instead advanced additional rationales in support of those measures. Plaintiffs filed this lawsuit on September 30, 2015, challenging those premarket review requirements on statutory and constitutional grounds.

Based on publicly available information, Plaintiffs were aware at the time the case was assigned to this Court that the Court had previously been a partner in the Washington, D.C. office of Zuckerman Spaeder LLP. Plaintiffs were also aware that CTFK is a longstanding client of Zuckerman Spaeder and that Zuckerman Spaeder has represented CTFK and other anti-tobacco groups on issues related to FDA's regulation of tobacco. Based on that information and

the possibility that lawyers at Zuckerman Spaeder had worked on this matter while the Court was still a partner at the firm, Plaintiffs filed a Notice of Informational Request on October 21, 2015, inquiring specifically whether any Zuckerman Spaeder lawyer had advised CTFK on this matter while the Court was a partner at the firm. Notice of Informational Request, ECF No. 14 (Oct. 21, 2015).

The Court responded on October 30, 2015, confirming that “[w]hile the court was a partner of the firm, Zuckerman Spaeder provided legal counsel to CTFK relating to the comments that it submitted to the FDA in June 2013 about the draft Guidance.” Response at 1.<sup>2</sup> “That legal advice pertained to, among other things, the ‘Label Changes’ Question & Answer section of the draft Guidance.” *Id.* The Court also disclosed that the Court’s “spouse presently is a partner at Zuckerman Spaeder and was a partner in 2013, when the firm provided legal advice to CTFK about the draft Guidance.” *Id.* at 2.

### ARGUMENT

This Court’s Response makes clear that lawyers from Zuckerman Spaeder advised CTFK with respect to its comments on FDA’s Draft Directive in 2013, which urged FDA to take the regulatory action that is under judicial review here. That disclosure requires recusal under Section 455(b)(2) because lawyers at Zuckerman Spaeder provided legal advice on this matter while the Court was a partner at the firm. It also requires recusal under Section 455(a) because Zuckerman Spaeder’s legal advice to CTFK regarding the regulatory requirements that Plaintiffs are challenging here—together with the firm’s other extensive anti-tobacco activities and the

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<sup>2</sup> Although the Court’s Response suggests that CTFK submitted comments on the Draft Directive in June 2013, the administrative record indicates that CTFK’s second set of comments on the Draft Directive was submitted on April 4, 2013. Administrative Record Index, at 2 (Entry No. 26); *see also* AR214-95. Because it does not appear from the administrative record that CTFK submitted any additional comments on the Draft Directive in 2013, Plaintiffs assume that the CTFK comments from April 2013 are those on which Zuckerman Spaeder lawyers provided legal advice.

Court’s close personal connections with the firm—provide grounds on which this Court’s impartiality might reasonably be questioned.

**I. RECUSAL IS REQUIRED UNDER SECTION 455(B)(2).**

Section 455(b)(2) provides that a judge “shall . . . disqualify himself” where “a lawyer with whom he previously practiced law served during such association as a lawyer concerning the matter [in controversy].” 28 U.S.C. § 455(b)(2). Section 455(b)(2) establishes a “broad[ ] ‘associational’ rule for recusal based on prior law firm employment,” *Baker & Hostetler LLP v. U.S. Dep’t of Commerce*, 471 F.3d 1355, 1358 (D.C. Cir. 2006), and imposes mandatory recusal obligations that are not waivable by the parties. 28 U.S.C. § 455(e); *see also Liteky v. United States*, 510 U.S. 540, 567 (1994) (Kennedy, J., concurring) (“Section 455(b) delineates specific circumstances where recusal is mandated.”). In “a close case” under Section 455(b)(2)—or any other provision of Section 455—“the balance tips in favor of recusal.” *United States v. Holland*, 519 F.3d 909, 912 (9th Cir. 2008).

The broad language of Section 455(b)(2) is not limited to circumstances in which a law firm with which the judge was previously affiliated worked on the particular case pending before the judge but extends to any situation where the law firm worked on the “matter in controversy.” 28 U.S.C. § 455(b)(2). Congress’s choice of the word “matter” makes clear that Section 455(b)(2) applies more broadly than to work done on a particular case with a specific docket number. *See, e.g., Little Rock Sch. Dist. v. Armstrong*, 359 F.3d 957, 960 (8th Cir. 2004) (“[T]he phrase ‘matter in controversy’ must mean something other than the word ‘case.’”); *United States v. Lawson*, No. 3:08-21-DCR, 2009 WL 1702073, at \*2 (E.D. Ky. June 17, 2009) (same); *see also* Black’s Law Dictionary 1126 (10th ed. 2014) (defining “matter” as “[a] subject under consideration, esp. involving a dispute or litigation”). Indeed, “[t]hroughout the *other* provisions of section 455, Congress made disqualification depend upon the judge’s suspect relationship

with the narrow ‘case’ or ‘proceeding’ before him.” *In re Letters Rogatory from Supreme Court of Ontario*, 661 F. Supp. 1168, 1174 (E.D. Mich. 1987) (emphasis added). In Section 455(b)(3), for example, Congress required recusal where the judge “served in governmental employment and in such capacity . . . expressed an opinion concerning the merits of the particular *case* in controversy.” 28 U.S.C. § 455(b)(3) (emphasis added). Congress’s use of the word “matter”—rather than “case”—in Section 455(b)(2) therefore indicates that “disqualification is required where the proceeding relates in any broad sense to the suspect matter, even though such has not been made part of the current proceeding.” *In re Letters Rogatory*, 661 F. Supp. at 1174; *see also Russello v. United States*, 464 U.S. 16, 23 (1983) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”).<sup>3</sup>

Numerous courts have concluded that recusal was required where lawyers with whom the judge previously practiced provided legal advice on the general matter pending before the judge—even if the advice was not given in connection with the specific case in question and the judge himself had no prior involvement in the matter. In *In re Rodgers*, 537 F.2d 1196 (4th Cir. 1976), for example, the Fourth Circuit held that recusal was required where a district judge’s former law partner had participated in drafting legislation that the defendants in the case were accused of using unlawful means to persuade the state legislature to enact. *Id.* at 1197-98. The court interpreted the term “matter” in Section 455(b)(2) broadly, holding that “the actual case before the court consists of more than” the specific charges alleged by the government and that

<sup>3</sup> “Matter in controversy” is broad enough to cover comments on administrative actions. When Congress wants to exclude administrative proceedings from the scope of a statute, it includes specific language to that effect, but included no such limiting language in Section 455(b)(2). *See, e.g.*, 18 U.S.C. § 207(a) (conflict-of-interest provision applicable to a “particular matter . . . which involved . . . *specific parties*”) (emphasis added).

the involvement of the judge's former law partner in enacting the legislation at issue required recusal under Section 455(b)(2), even though "[t]he judge knew nothing about these" activities. *Id.* at 1197; *see also Little Rock Sch. Dist.*, 359 F.3d at 960 (evaluating recusal motion under Section 455(b)(2) by determining whether the work done by a judge's former colleagues "touch[ed] upon the merits of the case").

Similarly, in *Preston v. United States*, 923 F.2d 731 (9th Cir. 1991), the Ninth Circuit ordered recusal where the district judge's former law firm had been representing a client with a potential financial interest in the litigation while the judge was still associated with the firm. *Id.* at 735. The court reached this conclusion even though there was no suggestion that the judge himself had worked on the matter and the firm's client "was not a named party to the suit before [the district judge]." *Id.* at 734-35; *see also Oriental Fin. Grp., Inc. v. Fed. Ins. Co.*, 450 F. Supp. 2d 169, 171 (D.P.R. 2006) (concluding that recusal was required under Section 455(b)(2), even though the judge did not participate in the matter before him while he was at the law firm, because the judge "had access to most, if not all, areas of the litigation division" when at the firm and spent "most of his working and lunch time with partners and associates of said division").

Here, the Court has disclosed that "[w]hile the court was a partner of the firm, Zuckerman Spaeder provided legal counsel to CTFK relating to the comments that it submitted to the FDA in June 2013 about the draft Guidance," including the "'Label Changes' Question & Answer section of the draft Guidance." Response at 1. Recusal is therefore required under Section 455(b)(2) because, during the time that the Court was a partner at Zuckerman Spaeder, lawyers at the firm "served as . . . lawyer[s] concerning the matter [in controversy]." 28 U.S.C. § 455(b)(2). Recusal is mandatory even though the Court did not participate in, and was not aware of, Zuckerman Spaeder's legal advice to CTFK regarding its comments on the Draft



Directive, *see Rodgers*, 537 F.2d at 1197, and even though CTFK itself is not a named party to this lawsuit, *see Preston*, 923 F.2d at 734-35. It is sufficient to require recusal under Section 455(b)(2) that, during this Court's tenure at the firm, Zuckerman Spaeder provided legal advice to CTFK regarding comments urging FDA to take the very regulatory action that is under judicial review in this case. In fact, CTFK's comments were submitted in direct response to, and took explicit issue with, the comments submitted by Plaintiffs PM USA and USSTC, which set forth many of the same arguments that Plaintiffs are raising in this litigation. *Compare* AR166 ("A requirement that manufacturers make premarket submissions for label and packaging changes would be contrary to the statute.") (capitalization altered), *and id.* at 171-72 ("An interpretation of the [Tobacco Control Act] that would require manufacturers to obtain FDA authorization before changing the names of their products would impose a constitutionally suspect prior restraint."), *with* Compl. at 20 ("The Second SE Directive conflicts with the structure and text of the [Tobacco Control Act] and exceeds FDA's authority.") (capitalization altered), *and id.* at 26 ("The Second SE Directive violates the First Amendment.") (capitalization altered); *see also* AR266-67 (comments of CTFK criticizing PM USA and USSTC's statutory and First Amendment arguments). All of those comments are now part of the administrative record in this case. Because Zuckerman Spaeder's legal advice therefore unquestionably "touch[ed] upon the merits of the case," it pertained to the same matter in controversy and necessitates recusal under Section 455(b)(2). *See Little Rock Sch. Dist.*, 359 F.3d at 960.

## **II. RECUSAL IS REQUIRED UNDER SECTION 455(A).**

Recusal is also required under Section 455(a) because Zuckerman Spaeder's comments on the regulatory requirements that Plaintiffs are challenging in this case, its longstanding involvement in anti-tobacco causes, and the Court's close personal ties to the firm create the appearance of partiality.

Section 455(a) requires a judge to “disqualify himself in any proceeding in which his impartiality might reasonably be questioned.” 28 U.S.C. § 455(a). Section 455(a) is “broader” in scope than Section 455(b) and requires recusal for the mere “appearance of partiality.” *Liteky*, 510 U.S. at 567 (Kennedy, J., concurring). The standard does not turn on whether the judge actually is biased. As the D.C. Circuit has explained, “a showing of an appearance of bias or prejudice sufficient to permit the average citizen reasonably to question a judge’s impartiality is all that must be demonstrated to compel recusal.” *United States v. Heldt*, 668 F.2d 1238, 1271 (D.C. Cir. 1981); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 114 (D.C. Cir. 2001) (“The question is whether a reasonable and informed observer would question the judge’s impartiality.”). In evaluating whether there is an appearance of partiality under Section 455(a), courts “are guided by the situations outlined in § 455(b), because affiliations that pose risks similar to those identified in § 455(b) may call for disqualification under § 455(a).” *In re Hatcher*, 150 F.3d 631, 637 (7th Cir. 1998) (internal quotation marks omitted).

Even if the Court were to conclude that Section 455(b)(2) does not apply by its terms, Zuckerman Spaeder’s legal advice to CTFK regarding the Draft Directive poses a similar risk to judicial impartiality as the circumstances specified in Section 455(b)(2) and would lead “a reasonable and informed observer [to] question the [Court’s] impartiality” in this case. *Microsoft Corp.*, 253 F.3d at 114. District judges have recused themselves under Section 455(a) in similar circumstances. In *Hampton v. Hanrahan*, 499 F. Supp. 640 (N.D. Ill. 1980), for example, the district judge recused himself because a partner in his former firm represented the firm on the board of a nonprofit organization that, during the judge’s time in private practice, had retained outside counsel at another firm to file an *amicus curiae* brief on the organization’s behalf in an earlier phase of the case. *Id.* at 642-44. Even though the judge’s former partner had not served

as a lawyer on the matter—and Section 455(b)(2) therefore did not apply—the judge concluded that recusal was required under Section 455(a) because his “impartiality might reasonably be questioned” due to his former partner’s involvement in the organization’s decision to participate in the case as an *amicus*. *Id.* at 645. Similarly, in this case, even if the comment process on the Draft Directive and this litigation do not constitute the same “matter” for purposes of Section 455(b)(2), Zuckerman Spaeder’s legal advice in connection with CTFK’s comments on the Draft Directive is “so closely related to [this matter] that [a] hypothetical reasonable person would question the judge’s impartiality.” *In re Hatcher*, 150 F.3d at 638.

The Court’s ties with Zuckerman Spaeder—and the firm’s additional connections to anti-tobacco groups and causes—underscore the appearance of partiality. The Court has disclosed that “his spouse presently is a partner at Zuckerman Spaeder and was a partner in 2013 when the firm provided legal advice to CTFK about the draft Guidance.” Response at 2. It is well-established that family connections to law firms involved in pending matters can be sufficient to trigger recusal. *See SCA Servs., Inc. v. Morgan*, 557 F.2d 110, 113-14 (7th Cir. 1977) (holding that recusal was required because the judge’s brother was a partner at a law firm that had entered an appearance on behalf of one of the parties before the judge).

Moreover, Zuckerman Spaeder’s legal advice to CTFK on the Draft Directive is not an isolated association with anti-tobacco organizations and causes. The firm has a longstanding history of providing legal advice to anti-tobacco groups and publicly staking out anti-tobacco positions. For example, while the Court was an attorney at the firm, Zuckerman Spaeder represented a “leading public health group in negotiations over legislation to give the FDA jurisdiction over tobacco products, culminating in enactment of 2009 tobacco legislation”—the same legislation on which FDA relied in issuing the Second SE Directive—and now “advises

this group regarding FDA implementation of the new law.” Food & Drug, Zuckerman Spaeder LLP, <http://www.zuckerman.com/practices-Food-and-Drug-FDA.html?p=28> (last visited Nov. 9, 2015). In addition, during the Court’s tenure at the firm and thereafter, lawyers at Zuckerman Spaeder have filed *amicus curiae* briefs and made public presentations in support of anti-tobacco groups and causes. *See, e.g.*, Brief of *Amici Curiae* Public Health Groups in Support of Defendants-Appellants, *Lorillard, Inc. v. FDA*, No. 14-5226 (D.C. Cir.), available at <http://goo.gl/bZtnNT>; Brief of *Amici Curiae* American Academy of Pediatrics et al., *Smoking Everywhere, Inc. v. FDA*, No. 10-5032 (D.C. Cir.), available at <http://goo.gl/aoclqc>; Carlos T. Angulo, Zuckerman Spaeder LLP, *Tobacco Product Standards: A Public Health Perspective* (Oct. 21, 2014) (referring to “the tobacco industry’s hugely successful and cynical effort to promote ‘low-tar’ and ‘light’ cigarettes as healthier tobacco products” and noting that “FDA/CTP is looking into these issues now and has publicly stated that these are three priority areas for potential 907 product standards”), available at <http://goo.gl/G1VTnF>. In light of Zuckerman Spaeder’s extensive connections to anti-tobacco causes both during and after the Court’s time at the firm—and the fact that the Court’s spouse remains a partner at the firm—an “average citizen reasonably [would] question [the Court’s] impartiality” in this case. *Heldt*, 668 F.2d at 1271. Recusal under Section 455(a) is therefore required.

### CONCLUSION

Plaintiffs respectfully request that the Court recuse itself pursuant to 28 U.S.C. § 455(a) and (b)(2) and cause another judge to be assigned to this case.

Dated: November 10, 2015

Respectfully Submitted,

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